Section 12. Appendices

Appendix 1: Emergency Fire Response, The Rocky Mountain Laboratories Integrated Research Facility

An Emergency Fire Response is an informed response to a possible fire occurrence.

HAMILTON FIRE DEPARTMENT

- HFD Responders shall respond to the RML northeast main entrance facing 4th Street.
- HFD Responders shall report to the NIH Police Security Station at the main campus access gate.
- HFD access card and keys are located in the Knox Box at the Police Security Station inside Building 30 and will be provided upon HFD arrival.
- NIH Police shall escort HFD Responders to area of concern.
- HFD Responders shall perform standard operating duties dependent on the occurrence area.

NOTE: HFD Responders SHALL NOT shut off or disable equipment that is in use without approval of the Onsite Safety Representative.

SPECIAL RESPONSE DIRECTIVES for Biosafety Level 3 (BSL-3), Animal Biosafety Level 3 (ABSL-3) and Biosafety Level 4 (BSL-4) secured areas.

- The Senior HFD Officer and NIH Police Supervisor shall enter into the interior corridors only (not inside rooms) of the BSL-3 and ABSL-3 secured areas to investigate status of occurrence.
- HFD Responders shall enter the BSL-3 or ABSL-3 secured areas only when granted access by the RML Biosafety Officer.

NOTE: The RML Biosafety Officer is the NIH Authority Having Jurisdiction (AHJ) concerning the physical and operational aspects of the Biosafety Level Laboratories.

- Fire responders are to utilize standard fire fighting personal protective equipment and self-contained breathing apparatus in the BSL-3 and ABSL-3 secured areas.

NOTE: All HFD Responders that enter BSL-3 and ABSL-3 secured areas are to remain in the corridor. The RML Biosafety Officer shall determine when responders and equipment are decontaminated and safe to leave the occurrence

area.

- HFD Responders SHALL NOT ENTER and SHALL NOT ATTEMPT to extinguish fire on 2nd floor of the BSL-4 secured area.
- HFD Responders are to remain on site until the RML Biosafety Officer determines the emergency no longer exists.

NIH POLICE:

- NIH Police Dispatch shall notify NIH Police Supervisor, Facilities Personnel, the RML Biosafety Officer, and the IRF Occupant Emergency Coordinator
- NIH Police Officer at the Security Station shall access the Knox Box and ensure appropriate keys and proximity access cards are moved to the main gate security office.
- NIH Police officer will direct HFD to the main entrance of the IRF.
- NIH Police Officer shall remain at IRF Police Security Station and assist in staging of responding personnel unless otherwise directed by NIH Police Supervisor.
- NIH Police Supervisor shall escort HFD Responders to appropriate non-secured areas.
- The Police Supervisor and Senior HFD Officer may enter into the interior corridors only (not inside rooms) of the BSL-3 and ABSL-3 secured areas to investigate status of occurrence.
- NIH Police shall perform crowd and traffic control of surrounding area.

RML BIOSAFETY OFFICER

- Shall respond to all known emergency occurrences
- Advise Senior HFD Officer on lab hazards
- Determine when the emergency is abated
- Insure proper decontamination has been performed on all response personnel and equipment that entered secured area before allowing to leave NIH occurrence site

RML FACILITIES STAFF:

- Respond appropriately to Integrated Research Facility when notified of emergency

- Report to the Police Security Station at the main entrance
- Remain at Security Station for direction from Senior HFD Officer or NIH Police Supervisor

Appendix 2: Fire Response Orientation, The Rocky Mountain Laboratories Integrated Research Facility

BUILDING DESCRIPTION:

The Integrated Research Facility (IRF) is a combination of two distinct building, building 25 and the recent construction of Bldg 28 which are independent areas but comprise the functioning units of the entire facility. These buildings in combination provide a very complex and sophisticated moderate to high containment facility designed to provide the safest of research facilities in the United States. The total facility is 124,588. The types of occupancy include BSL-2, BSL-3, and BSL-4 containment laboratories, ABSL-3 and ABSL-4 small animal isolation facilities, administrative and mechanical support areas.

Building 25 *(Floor Plan 1)*

Building 25 consists of two floors. The first floor consists of 3,315 sq ft of BSL-3 laboratories, 4,691 sq ft of ABSL-3 small animal isolation, and 1,722 sq ft of small animal support functions. The second floor consists of 9,728 sq ft of mechanical support.

Building 28 *(Floor Plans 2,3,4)*

Building 28 is divided into two separate functional areas. The north side of the facility consists of two floors.

- The first floor consists of administrative support, security and BSL-2 laboratories.
- The second floor consists of scientific office space, and BSL-2 laboratories. The combined BSL-2 laboratory space is 14,650 sq ft.
- On the second floor is also 2,950 sq ft of BSL-3 space.
- There are stairs located at both the East and West ends of the building.
- There is an elevator located on the West end of the building (1A162)

The south side of building 28 consists of three floors and a mechanical mezzanine that is considered the Maximum Containment area of the facility. While the first floor contains mechanical support and office areas there are a few key locations in this area.

- The sprinkler tree is located in Rm 1B102B
- The Emergency Power switch gear are located in Rm 1B165
- The Main Electrical switch gear is located in Rm 1B163
- There are two corridors (1B130B and 1B100B) that connect Bldg 28 to Bldg 25.

The second floor consists of BSL-4 laboratories and ABSL-4 small animal isolation rooms. This area is highly restricted and requires escort by security personnel and the Biocontainment Specialist.

The third floor and mechanical mezzanine contains Air handling equipment, HEPA

filtration housings, Exhaust fans, Chemical disinfectant storage, breathing air compressors supporting the BSL-4 facilities as well as backup breathing air systems.

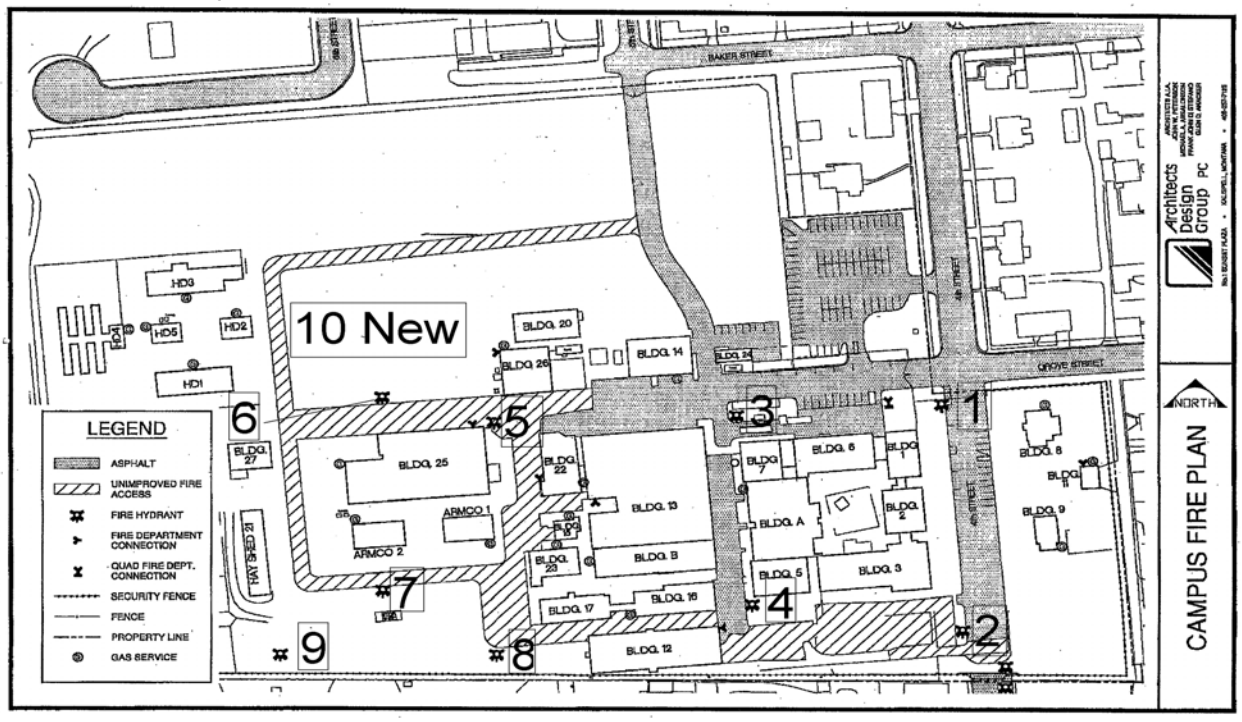
- There are stairs on the North side leading from the Lobby area to the corridor (2A108C) and on the North West end (2B171)
- There is an elevator on the South east corner (1B150E)

FIRE HYDRANT INFORMATION:

- Hydrants are supplied by 6" water main.

FIRE HYDRANT FLOW (test date-2001)

HYDRANT NUMBER AND LOCATION	STATIC PSI	RESIDUAL PSI	PSI/GPM FLOW RATE
Flow Hydrant: #6/Test Hydrant: #5	**57 PSI**	**46 PSI**	**20/1,470 GPM**
Flow Hydrant: #9/Test Hydrant: #7	**57 PSI**	**42 PSI**	**20/ 1,200 GPM**
Flow Hydrant: #4/Test Hydrant: #8	**59 PSI**	**42 PSI**	**20/ 1,130 GPM**
Flow Hydrant: #3/Test Hydrant: #5	**57 PSI**	**35 PSI**	**20/ 1,400 GPM**
Flow Hydrant: #2/Test Hydrant: #4	**57 PSI**	**44 PSI**	**20/1,340 GPM**
Flow Hydrant: #1/Test Hydrant: #2	**60 PSI**	**48 PSI**	**20/1,430 GPM**



SPRINKLER AND STANDPIPE EXTERIOR CONNECTIONS:

- Located on exterior north east corner of Bldg 25
- Located on exterior northwest corner of Bldg 28

STAGING AREA AND ENTRY:

- The main entrance northeast corner of the IRF is the staging area for the HFD.
- The interior staging location is the Police Security Station in the corridor next to the main entrance of the IRF.

FACILITY ACCESS KNOX BOX:

- The Knox Box for Hamilton Fire Department (HFD) access is located at the Police Security Station.

HAMILTON FIRE DEPARTMENT (HFD) SECURITY ACCESS:

Building Key Access: (2 keys)

- Keys are located in Knox Box.
- Allows access to mechanical rooms
- Allows access to roof and attic doors

Card Access:

- HFD access card is located in Knox Box at the Police Security Station.
- Card will allow full access to the IRF except for the BSL-3 and ABSL-3, BSL-4 and ABSL-4 areas.

Elevator Key:

- Key is located in the elevator Knox Box.

FIRE ALARM NOTIFICATION PANELS:

- Alarm notification panel for Building 25 is located East main entrance door on the West wall as you enter.
- The alarm notification panel for Building 28 is located at the security control desk as you enter the main entrance on the North East corner of the IRF.

***NOTE:* Fire Alarm Panels in alarm mode *DO NOT DEACTIVATE* security access devices**

SPRINKLER SYSTEM:

- All areas of IRF are covered by a sprinkler system.
- The sprinkler system riser, control valves and fire pump are located in Rm 1B102B

STAND PIPE RISERS:

- Located in east and west stairwells in the IRF with 2½" fire connection on each riser at each floor

FIRE CABINETS:

- Cabinets are NOT equipped with hose.
- Cabinets are equipped with portable fire extinguishers.

MAIN GAS SHUT-OFF VALVE:

- Gas Meter shut-off is located midway exterior on south side of the IRF.
- The in ground service valve is located 30ft due south of meter with yellow valve cover marked GAS.

INDIVIDUAL LABORATORY GAS SHUT-OFF VALVES:

- Gas shut-off valves to individual laboratories utilizing gas, are located near the laboratory's door that is served. Valves are very visible and marked with the corresponding laboratory room number.

ELECTRICAL MAIN POWER SWITCHES:

- Main switches for the IRF are located in Rm 1B163

ELECTRICAL EMERGENCY POWER:

- The IRF emergency power comes from Rm 1C100A (Bldg 25)

WATER SHUT-OFF VALVES: *(Drawing M-2B)*

- The fire water shut-off valve is located in 1B102B
- The domestic water shut-off valve is located in 1B102

HVAC SYSTEM:

- Sectional isolation valves are located in the mechanical rooms inside the IRF

RADIATION SOURCE:

- The Maximum Containment Area 1st floor Rm. 1B150B contains a Cobalt-60 irradiator.
- Millicurie amounts of radioactive sources both in sealed and unsealed forms are located in designated lab areas. *(Attach Map)*

ROOF AND ATTIC ACCESS:

- The IRF roof and attic accesses are located at the top of each stairwell.

EXTERIOR EMERGENCY EXIT DOORS:

- Exit doors are equipped with a 30 second delay (door bars must be held for a minimum of 3 seconds before door latch releases after 30 seconds).

***NOTE:* The latch will reset with door closure.**

INTERIOR EXIT DOORS:

- All doors entering stairwells in the IRF require card access to re-enter hallways**.**

MAN TRAPS:

- Mantraps are located in the IRF main entrance, the Bldg 25 first floor entrance to the Animal Biosafety Level 3 (ABSL-3) secured area. (*Need to list all mantraps in building)*
- MAJOR FIRE CONDITIONS: The Senior Fire Officer shall request NIH Police Supervisor to deactivate mantraps as needed.

Appendix 3: Emergency Medical Service Response, The Rocky Mountain Laboratories Integrated Research Facility

An Emergency Medical Service Response (EMS) is an informed medical emergency response to provide medical stabilization care and transportation.

EMERGENCY MEDICAL SERVICE:

- Hamilton Fire Department (HFD) shall respond to the Integrated Research Facility in the capacity of EMS First Responders and help stabilize person until arrival of EMS Ambulance Response.
- EMS shall respond to northeast main entrance facing 4th Street unless otherwise directed.
- EMS shall report to the NIH Police Security Station inside the main campus access gate.
- NIH Police shall escort EMS to the area of occurrence.
- EMS shall perform standard response practices.

SPECIAL RESPONSE DIRECTIVES for Biosafety Level 3 (BSL-3), Animal Biosafety Level 3 (ABSL-3), AND Biosafety level 4 (BSL-4) secured areas.

- EMS SHALL NOT ENTER INTO BSL-3, ABSL-3, or BSL-4 secured areas.
- EMS SHALL NOT HANDLE OR TRANSPORT person from the BSL-3, ABSL-3 or BSL-4 secured areas until the person is decontaminated by designated NIH personnel and deemed safe.
- EMS SHALL UTILIZE personal protective equipment during response and transport.

NIH BSL-3, ABSL-3 AND BSL-4 PERSONNEL:

- In the event a person in need of attendance is located in a secured area (BSL-3, ABSL-3 and BSL-4), a NIH representative shall decontaminate and deliver the person to the Isolation/Evaluation Suite Rm 1A120D (*Floor Plan 2)*.
- Transport of individuals may be restricted to an Isolation gurney as supplied by NIH-RML. This determination will be made by the RML Biological Exposure Assessment Team

NIH POLICE:

- NIH Police Dispatch shall notify the RML Biosafety Officer for all EMS emergencies in the Integrated Research Facility.
- NIH Police shall assist/escort the responding EMS to the IRF main entrance.
- NIH Police shall escort EMS inside facility to proper staging area of occurrence or Rm 1A120D.
- NIH Police shall perform crowd and traffic control of incident area

Appendix 4: RML Information Hotline Number: 406-375-9675

The Rocky Mountain Laboratories (RML) has an information hotline that may be accessed by RML staff members and the public 24 hours per day. Up-to-date messages are posted as needed to provide information on the status of campus operations. Examples of announcements could include inclement weather procedures for staff members such as delayed arrival information, closure of the campus, early dismissals, etc. In addition, instructions related to emergency response can be provided to keep callers informed of any special instructions for access to the RML campus.

Should severe weather conditions or an emergency situation affect normal operations at RML, various announcements to alert employees to such changes will be made. One of the messages below will be left with RML Security, the local radio station (KLYQ 1240 AM in Hamilton), the RML Hotline and through an RML-wide email message. Email can be checked off-campus by visiting http://owa.nih.gov

Possible Operating Statuses

- **RML IS OPEN FOR BUSINESS.**
  - **Employees are expected to report to work on time.**
- **RML IS OPERATING UNDER AN UNSCHEDULED LEAVE POLICY.**
  - **Employees who have NOT been designated as an EMERGENCY EMPLOYEE may take leave without prior approval. Check with your supervisor to find out if you are considered an emergency employee.**
- **RML IS OPERATING UNDER A DELAYED ARRIVAL POLICY.**
  - **Reasonable delays in reporting to work will be excused (no leave will be charged).**
- **RML IS CLOSED FOR THE DAY.**
  - **Staff NOT designated as an Emergency Employee are excused from duty without loss of pay or charge to leave.**

IF YOU ARE AN EMERGENCY EMPLOYEE: You are expected to report to work on time regardless of the above announcements. If you are already at work when notification of an adjusted work dismissal is received, you are to remain at work through the end of your tour.

The information hotline is updated as events warrant and is administered by the

RML Business and Program Manager who is responsible for overall campus operations.

Appendix 5: Emergency Evacuation Procedure Summary

This page will contain the current version of the Emergency Evacuation Procedure Summary.

Appendix 6: RML Incident Notification System (DRAFT)

PHASE	Examples of Events (the following are only examples and are not all-inclusive)	Possible Notifications and Activations (the following are only possible examples and specific actions are dictated by the particular situation)
Phase 0: Non-event Definition: Normal day-to-day activity	• Routine surveillance • Routine surveys and audits	• Normal reporting and maintenance of records • Routine meetings and communication with RML staff
Phase 1: RML Event Definition: An event occurring on the RML campus, but having no implications outside of RML campus	• Suspected exposure in BSL-1 or BSL-2 with no public health implications • Contained radiological, chemical, or biological spill of BSL-1 or BSL-2 material with no external or regulatory implications • Malfunction of alarm system that can be corrected internally • Scheduled or unscheduled utility shutdown or disruption • Event with public information implications, e.g., false alarm, personal injury requiring BV EMS	• Notify appropriate internal response staff • Notify RML Associate Director and/or OAD Business and Program Manager within 24 hours • Issue RML-wide email notice if warranted • Send notice to neighbors if warranted
Phase 2: Local Event Definition: An event originating on the RML campus, but having implications confined to the local community	• Confirmed work-related exposure or illness from BSL-2 infectious agent • HAZMAT/Environmental event with potential external or regulatory implications • Receipt of suspicious package, substance or mail • Event with public information implications, e.g., false alarm, personal injury requiring BVEMS • Event leading to damage of a facility	• Notify appropriate internal response staff • Notify RML Associate Director and/or OAD Business and Program Manager as soon as possible • Issue RML-wide email notice if warranted • Notify local authorities, e.g., health officer, public health, law enforcement, fire department, local government • Notify NIAID DIR, NIAID OCGR, and NIH DOHS • Update RML hotline, if warranted • Notify community contact list and CLG, if warranted • Notify public and media, if warranted
Phase 3: Event with Extended Impact Definition: An event originating on the RML campus with potential for urgent implications, long-term impact to RML and/or impact extending beyond local community	• Suspected exposure or confirmed work-related illness from BSL-3 or BSL-4 infectious agent • Dangerous person on site • Threat of terrorist activity on campus • HAZMAT/environmental/radiological event with external or regulatory implications • Event leading to significant facility damage or interruption of operations	• Notify appropriate internal response staff • Notify RML Associate Director and/or OAD Business and Program Manager as soon as possible • Issue RML-wide email notice • Notify local and federal authorities, e.g., health officer, public health, MDPHHS, MTDES, FBI, MDEQ, NRC, CDC, law enforcement, fire department, local government • Notify NIAID DIR and NIH DOHS • Update RML hotline • Notify community contact list and CLG • Notify public and media • convene Crisis Management Team • Convene BEAT • Convene RSOAC • Notify state and federal regulatory officials
Phase 4: External Event Definition: an event originating outside of RML campus with implications for RML	• Threat of natural disaster and/or severe weather • HAZMAT or environmental event with implications for RML campus • Utility interruptions • Civil disturbance in community ▪ Terrorist threat in community ▪ Infectious disease epidemic	• Notify appropriate internal response staff • Implement evacuation or lockdown procedures • Notify RML Associate Director and/or OAD Business and Program Manager as soon as possible • Issue RML-wide email notice • Notify local and federal authorities, e.g., health officer, public health, MDPHHS, MTDES, FBI, MDEQ, NRC, CDC, law enforcement, fire department, local government • Notify NIAID DIR and NIH DOHS • Update RML hotline • Convene Crisis Management Team • Convene RSOAC ▪ Notify public and media ▪ Convene B.E.A.T.

Appendix 6: RML INCIDENT NOTIFICATION SYSTEM (DRAFT) (CONT.)

Abbreviations used:

- BEAT: Biological Exposure Assessment Team
- BSL: Biosafety Level
- CDC: Centers for Disease Control
- CLG: Community Liaison Group
- DIR: Division of Intramural Research
- DOHS: Division of Occupational Health and Safety
- FBI: Federal Bureau of Investigation
- HAZMAT: Hazardous Materials Team
- MDEQ: Montana Department of Environmental Quality
- MDPHHS: Montana Department of Public Health and Human Services
- MTDES: Montana Disaster and Emergency Services
- NIAID: National Institute of Allergy and Infectious Diseases
- NIH: National Institutes of Health
- NRC: Nuclear Regulatory Commission
- OAD: Office of the Associate Director, RML
- OCGR: NIAID Office of Communication and Government Relations
- RML: Rocky Mountain Laboratories
- RSOAC: RML Security Operations Advisory Committee

Appendix 7: Maintenance and Inspection Schedules Suppression and Detection Systems (DRAFT)

Portable Fire Extinguishers

Task	**Inspection Frequency**
Inspect all portable fire extinguishers	Monthly
Service all portable extinguishers	Annually
Hydrostatically test Carbon Dioxide extinguishers	Every Five years
Empty and service pressure type extinguishers	Every Six Years
Hydrostatically test dry chemical extinguishers	Every Five years

Alarm Systems

Test	**Frequency**
Test Fire Alarm System	Monthly
Test Voice communications	Monthly
Inspect Stand-by Batteries	Monthly
Confirm signal to monitoring agency	Monthly
Records all testing of these systems	

Maintenance	
Inspect and service all alarm components	Annually
Inspect and service all components of voice communications system	Annually
Inspect and service monitoring agencies transmission device	Annually

Standpipe and Hose System

Maintained in operational readiness at all times. **Notify** the Fire department if shut down.

Wet Sprinkler System

Testing	**Frequency**
Operate and test water flow alarms	Monthly
Gate valve supervisory switches	6 Months
Water Flow alarms (inspectors test connection)	Annually
Main Drain Test	Annually

Maintenance	**Frequency**
All sprinkler water control valves	Weekly
Inspect all water control valves	Monthly

Emergency Generator Systems

Task	**Frequency**
Complete test of emergency generator	Weekly
Full Load Test	Annually

Means of Egress and Fire Separations

Task	**Frequency**
All fire doors are shut	Daily
Inspect operation of fire doors	Monthly

Fire Department Access
Ensure that the grounds and roads are kept in a manner to enable access year round to the facility.

Venting to Aid Firefighting

Test operation of smoke dampers	Every three months
Test controls to smoke venting systems	Every three months

Appendix 8: Register Of Mobility-Impaired Persons (DRAFT)

Room #	Name of person	Impairment	Evacuation Assistant(s)

1._____

2._____

3._____

4._____

5._____

6._____

7._____

8._____

9._____

10._____

Appendix 9: Bomb Threat Checklist (DRAFT)

Sex of Caller: _____ Race: _____ Age: _____ Length of Call:

_____

Number at which call was received: _____

Time: _____ Date: _____/_____/_____

CALLER'S VOICE:

___Calm	___Angry	___Excited	___Slow	___Rapid
___Soft	___Loud	___Laughter	___Crying	___Normal
___Distinct	___Slurred	___Nasal	___Stutter	___Lisp
___Raspy	___Clears Throat	___Breathes Deep	___Cracking	___Distinguished
___Accent	___Familiar			

Familiar? Who did it sound like?
_____

BACKGROUND NOISES:

___Street	___Dishes	___Voices	___Motor	___House
___Office	___Distinct	___Slurred	___Nasal	___Machinery
___Animals	___Clear Line	___Booth		
____Other_____				
___Music	___TV/Radio	___Store/Café	___Factory	___Stutter
___Lisp	___Static Line	___Long Distance		

THREAT LANGUAGE:

___Educated ___Foul ___Irrational ___Incoherent ___Taped ___Message read ___Other_____

Remarks_____

Department: _____ Phone number: _____

Appendix 10: RML Incident Investigation Report Form (DRAFT)

Employee Information:

Laboratory affiliation:_____

Supervisor's Name/Phone:_____

Person(s) involved Name/Phone:_____

Title:_____

E-mail address:_____

Training Information:

What Bio-safety training or information has this person received?_____

When and Where?_____

What previous practical experience has this person had?_____

When and Where?_____

Bio-safety Information:

Location of Incident:_____ Time:_____ Date:_____

Bld:_____ Room:_____

Is Bio-safety Signage complete and current? ☐ yes ☐ no

Infectious Agent:

Name:_____

Strain, isolate, etc:_____

Bio-safety level: ☐ BSL1 ☐ BSL2 ☐ BSL3 ☐ BSL4

Bio-safety Cabinet

Cabinet Number:_____

Date of Last Certification:_____

Is there a Standard Operating Procedure for this organism/procedure/facility? ☐ yes ☐ no

If yes attach copy. If no, should one be written?

Is there previous exposure record for this person/organism/facility? ☐ yes ☐ no

If so describe:_____

Incident Information:

Describe the procedure during which exposure may have occurred. Be specific and include possible route of exposure. Try to estimate the quantity of infectious agent involved in this exposure.

.

Disinfection and Treatment:

Describe what immediate treatment was given/recommended including disinfection procedures:

Was medical attention sought or recommended? ☐ yes ☐ no

Was person referred to physician? ☐ yes ☐ no
If possible, describe treatments and recommendations.

Describe what additional disinfection of the equipment/room/facility is needed:

Describe the risk that infectious agent was spread beyond the facility:

Describe the risk of residual infectious agent contamination:

Notification:

What authorities or supervisors were noted?

When?

Follow Up:

What additional follow-up is recommended?

Who will perform follow-up?

When will follow-up be done?

Other Pertinent information or counseling:_____

_____

_____

Sharps Injury:

Did the device in use have engineered sharps injury protection? ☐ yes ☐ no
Type/brand name of device involved in the exposure:

_____

Was the protective mechanism activated? ☐ yes ☐ no

Did the exposure occur before, during, or after activation? ☐ before ☐ during ☐ after

When did the exposure incident occur? (check one)

- ☐ During use of sharp
- ☐ Between steps of a multi-step procedure
- ☐ After use and before disposal of sharp
- ☐ While putting sharp into disposal container
- ☐ Sharp left in inappropriate place
- ☐ Overfilled sharps container
- ☐ Disassembling
- ☐ Other _____

_____ _____
Signature of Person Conducting Investigation/Title Date

_____ _____
Signature of Chairperson, Biosafety Committee reviewed by BSC Date

(Do not sign until a thorough review of the incident by the Bio-Safety Committee is complete and corrective actions are in place.)
Completed copies of this form must be routed to the Bio-Safety Committee and kept on file.

Appendix 11: RML Biological Exposure Control Plan (DRAFT)

Rocky Mountain Laboratories Biological Exposure Control Plan

Version 2.0

Effective Date: _____

This version supersedes all previous versions

Certification of annual review and approval:

_____

Nancy Hoe Date
Biosafety Officer
Rocky Mountain Laboratories

_____

Paul Carlson Date
Occupational Safety and Health Manager
Rocky Mountain Laboratories

_____

Sue Priola Date
Chairperson
Institutional Biosafety Committee
Rocky Mountain Laboratories

Section 1. Introduction

The Rocky Mountain Laboratories (RML) is a component of the Division of Intramural Research of the National Institute of Allergy and Infectious Diseases (DIR NIAID). Research at RML currently involves the study of infectious agents at Biosafety Levels 1, 2 and 3 (BSL-1, BSL-2 and BSL-3). With the completion of the Integrated Research Facility (IRF), scientists at RML will also have the opportunity to work with infectious agents classified at BSL-4.

The majority of research studies at RML are performed at BSL-2 in standard laboratories. Work with BSL-2 agents is considerably less hazardous than with BSL-3 or BSL-4 agents; nevertheless, biological exposures can occur while working with these infectious agents. Research studies at BSL-3 and BSL-4 require highly trained personnel, detailed research protocols, and highly specialized biocontainment facilities. Historically, these labs have proven to be extremely safe; however, there have been incidents in which staff members have been exposed to infectious agents, or, in very rare instances, have developed work-related infectious diseases. Detailed information about BSL-2, BSL-3 and BSL-4 agents and facilities may be found in the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories (4th ed)" (BMBL).

Biological incidents may result from laboratory accidents, improper functioning or operation of laboratory or biocontainment equipment, or improper functioning or operation of equipment utilized for decontamination of biological agents in biocontainment facilities. In order to minimize the potential for biological incidents in experimental research studies, multiple levels of operational safeguards are utilized. At RML, an **Exposure Control Plan** (**ECP**) has been developed that outlines the institutional oversight and management of potential exposures to infectious agents.

RML employees are also potentially at risk of infection and subsequent illness as a consequence of exposure to human blood or other potentially infectious body fluids. Therefore, this ECP has also been developed to minimize employee exposures to blood-borne pathogens such as HBV and HIV. The ECP establishes the policy for the implementation of procedures that relate to the control of infectious diseases that may be contracted by the blood-borne route. The ECP is in compliance with the Occupational Health and Safety Administration (OSHA) Blood Borne Pathogens

Standard (29 CPR 1910.1030), and serves as both the written program, for compliance purposes, and as a training document.

The ECP shall be administered and reviewed annually by the RML Biosafety Officer and the Institutional Biosafety Committee (IBC). A copy of the ECP is made available to all RML employees, upon request, by contacting the Biosafety Officer at extension 334, or the Occupational Safety and Health Manager at extension 431.

Section 2. Exposure Response and Management

Exposure Response

Exposure Reporting Responsibilities

The ultimate responsibility for reporting exposures, spills, and other biological hazards rests with the Principle Investigators, supervisors, and the RML employees.
Such exposures and hazards need to be reported to supervisors, principal investigators, the Biosafety Officer and the Occupational Safety and Health Manager immediately upon becoming aware of the situation. The following serve as examples:

- The ultimate responsibility for reporting an exposure to a potentially infectious material rests with the RML employee who has been exposed.
- Notifying employees of the presence of potentially infectious materials in any workplace is the responsibility of the Principal Investigator or supervisor in charge of the work area.
- Notifying emergency services of spills is the responsibility of all RML employees.

It is strongly suggested that employees notify their personal physician or appropriate healthcare worker of their place of employment and the agent with which they work. In addition, all personnel are to report immediately to their supervisor, the RML Biosafety Officer or the RML Occupational Safety and Health Manager any signs or symptoms of disease that might be a result of exposure to agents with which they work.

RML Management responsibilities and procedures following an exposure are described below (see **RML Biological Exposure Assessment Program (RML BEAP)**).

Emergency Steps to Take in the Event of an Exposure

- If an employee sustains a potential exposure to an infectious agent including HIV or other bloodborne pathogens, **immediate first aid** should be initiated before leaving the worksite (see below).
- As soon as is practical **after** rendering immediate first aid, notify the lab supervisor, if he or she is immediately available.

- If emergency medical care or transport is needed call 9-911 or 0 for RML security.
- Report to the Biosafety Officer (x334) or Occupational Safety and Health Manager (x431) as soon as possible after the exposure.

First Aid to be Rendered On Site at the Time of an Exposure

Needlestick and sharps injuries of all depths and types

1. Expose the affected area sufficiently to determine the size of injury and to render additional care
2. If the wound has penetrated intact skin attempt to express blood from the wound **while proceeding to a wash station** and again **after** washing.
3. Wash the area immediately with copious amounts of antibacterial soap or povidone iodine solution (such as Betadine) and water
4. Place an antiseptic ointment over the affected area.
5. Do not use caustics such as bleach etc. on any open wound as they may damage the skin and increase chances of infection as well as delay wound healing.

Mucous membrane splash

- Contaminated eyes and mucous membranes should be irrigated for 15 minutes using normal saline or water.

Bite from an infected animal

1. Expose the affected area sufficiently to determine the size of injury and to render additional care
2. If the wound has penetrated intact skin attempt to express blood from the wound **while proceeding to a washing station** and **after** washing.
3. Wash the area immediately with copious amounts of antibacterial soap and water
4. Place an antiseptic ointment over the affected area.
5. Do not use caustics such as bleach etc. on any open wound as they may damage the skin and increase the chances of infection as well as delay wound healing.

- Laboratory animals carry their own indigenous flora, which has the potential to cause infection after a bite. At least 85% of wounds from animal bites harbor bacteria, and one cannot reliably predict which wound will become infected. For this reason **antibiotic prophylaxis is indicated for any bite**.
- While Asian macaque monkeys have been identified as natural carriers of Herpesvirus simiae (B virus), which has the potential to be a devastating

human pathogen, the macaque colony at RML is unique in being B virus free. Thus monkey bites will be treated as above.

- All laboratory workers should have their tetanus immunization status reviewed at the time of the bite, and updated if indicated.

Scratch from an infected animal

1. Expose the affected area sufficiently to determine the size of injury and to render additional care.
2. If the wound has penetrated intact skin attempt to express blood from the wound **while proceeding to a washing station** and **after** washing
3. Wash the area immediately with copious amounts of antibacterial soap and water
4. Place an antiseptic ointment over the affected area.
5. Do not use caustics such as bleach etc. on any open wound as they may damage the skin and increase the chances of infection as well as delay wound healing.
6. All but the most superficial of scratches should receive a course of antimicrobials

Post-Exposure Evaluation and Follow-up

In the event an employee sustains a potential exposure to an infectious agent including HIV or other bloodborne pathogens, the Biosafety Officer will notify the RML Infectious Disease Adviser, and they will make the initial evaluation of an exposure, including whether to notify the RML Associate Director or to convene the RML BEAP (see below). If deemed necessary, post-exposure evaluation and follow-up will be provided by Marcus Daly Community Hospital or the Regional Referral Hospital (RRH) for RML employees.

The Biosafety Officer and the Infectious Disease Advisor will be following the care provided to assure appropriate care is given. The Infectious Disease Advisor will serve as medical consultant or attending physician in emergency management, short-term care, and follow up of any laboratory acquired infection as needed and requested by the Biosafety Officer or Associate Director for RML. In addition, any occupational exposure to an infectious agent must be reported to the RML Occupational Safety and Health Manager (OSHM). The RML OSHM will complete US Department of Labor Form CA-2, “Notice of Occupational Disease and Claim for Compensation”.

If required, employee counseling is provided free of charge through the Employee Assistance Program (AEP) administered by Federal Occupational Health. Their 24-hour hotline number is 1-800-222-0364. If you contact them, please indicate that you work for RML and that you are part of NIH.

Emergency care will be provided to visitors and contract personnel who sustain a

potential exposure. These individuals will be referred to their private or company physicians for follow-up.

Post-Exposure Incident Review

In the event an employee sustains a potential exposure to an infectious agent including HIV or other bloodborne pathogens, the Biosafety Officer as well as the employee's supervisor will review the incident. In certain cases, the review will involve members of the RML BEAP (see below). The RML Biological Incident Investigation Form (Appendix 1) will be utilized.

As part of the incident review, a sharps injury log will be maintained for the recording of percutaneous injuries and mucous membrane exposures. The log contains information on the type and brand of device involved in the incident; the department and work area where the incident occurred; and an explanation of how the incident occurred. The log will be maintained by the Occupational Safety and Health Manager and used to gather information that may aid in the implementation of safer technologies. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee.

All work-related needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potential infectious material (as defined by 29 CFR 1910.1030) will be entered in the OSHA 300 Log as an injury using the OSHA 301 Injury and Illness Incident Report. All required records are kept for a minimum of five (5) years following the end of the calendar year that the records cover.

Exposure Management

RML Biological Exposure Assessment Program (RML BEAP)

In order to deal with the possibility that an incident, exposure or illness involving a work-related infectious agent might occur, the **Rocky Mountain Laboratories Biological Exposure Assessment Program (RML BEAP)** has been established. The RML Biological Exposure Assessment Program provides for local (RML) and institutional (NIAID/NIH) assessment of incidents, exposures and illnesses related to intramural use of biological agents, as well as on evaluation, therapy, recommendations, and corrective actions. The overriding concern of the program is to provide rapid and appropriate medical evaluation, treatment and prophylaxis for any exposed individual.

Although the RML BEAP functions semi-autonomously, ultimate responsibility and authority for these matters is vested with the Division of Occupational Health and Safety (DOHS), Office of Research Services (ORS), National Institutes of Health (NIH).

Membership of the RML BEAP

The following individuals are the members of the RML BEAP assigned to the RML campus:

- The Associate Director for RML
- The RML Senior Administrator or equivalent (position pending)
- The RML Biosafety Officer
- The RML Occupational Safety and Health Manager
- The RML Infectious Disease Adviser
- The relevant Principal Investigator(s) or supervisor(s)
- The relevant RML Laboratory Chief(s)
- The Chairperson of the RML Institutional Biosafety Committee

The following individuals are the members of the RML BEAP assigned to the Bethesda NIH campus:

- The Director of the NIAID Division of Intramural Research (NIAID DIR)
- A representative of the NIH Division of Occupational Health and Safety (NIH DOHS)

The following individuals will be notified and/or added to the RML BEAP as needed on an ad hoc basis:

- The Responsible Official for the RML Select Agent Program
- The Chief of the Rocky Mountain Veterinary Branch
- The leader of the RML Hazmat Team
- The RML Radiation Safety Officer
- The Ravalli County Health Officer
- Ravalli County Public Health Nursing Department
- The RML Communications and Public Liaison Officer

Operations of the RML BEAP

The Exposure Response Plan and the specific SOPs dictate the obligations for RML workers to report biological incidents, potential exposures and/or possible work related infectious diseases. These incidents may become evident in several ways:

- o Obvious release of or exposure to infectious materials or infected animals. For this purpose, a release is considered to be any loss of material outside of the primary containment.
- o Recognition of a possible work-related illness in the absence of any obvious signs of exposure as judged by an RML worker, contract employee, RML visitor, or his/her health care provider. (NOTE: The State of Montana requires all Montana health care providers to report patients diagnosed, or suspected, with any reportable disease to their county health departments.)
- o Failure of biocontainment or failure to execute proper biosafety practices and procedures.

- Identification of a possible work-related reportable disease by the Ravalli County Public Health Nursing Department

The primary goal of this program is to provide the best possible medical care to any staff member who sustains an exposure to a biological agent. **Therefore, the first priority is to complete emergency first aid treatment and immediate clean up procedures.** Any detailed or specific information for evaluation, follow-up and surveillance is contained in the SOPs for particular infectious agents.

Notifications and Procedures

- It is the responsibility of each staff member and individual to report any such incident, as soon as is practical, to the laboratory supervisor and the RML Biosafety Officer.
- The Biosafety Officer will notify the RML Infectious Disease Adviser, and they will make the initial evaluation of an exposure.
  - The RML Biological Incident Investigation Form (Appendix 1) will be utilized.
  - A limited number of other individuals are also authorized to contact the Infectious Disease Adviser. In the event that the Infectious Disease Adviser is contacted, he/she will notify the RML Biosafety Officer.
  - The RML Infectious Disease Adviser will advise the RML Biosafety Officer on the need for any immediate evaluation, treatment, prophylaxis, or vaccination.
  - The RML Infectious Disease Adviser will advise the RML Biosafety on the need to involve the Regional Referral Hospital (RRH) or Bitterroot Valley Emergency Medical Services (BVEMS).
- Any occupational exposure to an infectious agent must also be reported to the RML Occupational Safety and Health Manager (OSHM). The RML OSHM will complete US Department of Labor Form CA-2, "Notice of Occupational Disease and Claim for Compensation" (http://www.dol.gov/esa/regs/compliance/owcp/ca-2.pdf).
- In the event that the incident involves a potential exposure or illness resulting from a BSL-3 or BSL-4 agent, the RML Biosafety Officer and the RML Infectious Disease Adviser will notify the Associate Director. The Associate Director will immediately notify the NIAID DIR and the NIH DOHS, and convene a meeting of the RML BEAP.
- In the event that the incident involves potential exposure or illness resulting from a BSL-2 agent, the RML Biosafety Officer and the RML Infectious Disease Adviser will notify the Associate Director. They will make a recommendation as to whether or not to convene a meeting of the RML BEAP.
- The Associate Director for RML is a Core Member of the Ravalli County Health Emergency Advisory Team (HEAT) (see below). In the event that the HEAT is activated, the Associate Director will convene a meeting of the RML BEAP.

- The RML BEAP will assess the incident and the exposure level, and will evaluate measures already taken or proposed to deal with the incident.
- In rare and exceptional circumstances, the NIH DOHS may elect to assume control of managing the exposure.
- The RML BEAP will assess any immediate threat or risk to laboratory operations, employees, facilities, the public and the environment, and will identify measures necessary to address, abate, or mitigate any residual or ongoing threat or risk. This will include determining the level of decontamination or any interruption of operations that might be required.
- In the event that it is determined that an incident poses a public health hazard, the Ravalli County Health Officer and the Ravalli County Public Health Nursing Department will be notified. The specific management of perceived or actual public health hazards is the province of the Ravalli County Public Health Nursing Department and the Ravalli County Health Emergency Advisory Team (HEAT). The role, membership, and methods for convening the HEAT are contained in Tab 5.50 of the Ravalli County Emergency Operations Guidelines. In brief, the HEAT team is the first group convened in the event of an actual or perceived public health emergency and will advise local emergency responders in their response to an incident. The Associate Director for RML is a Core Member of the HEAT.

  RML/NIH will cooperate as much as possible with state and local officials in responding to any incident arising at RML that the BEAP determines poses a public health hazard. Assistance will be provided whether the incident arises from possible exposure of a staff member at RML, a contractor, or a visitor. Both state and local officials have authority over public health matters, and RML/NIH does not intend to usurp these agency's authorities. While the NIH Is restricted under Federal law from agreeing to pay expenses in advance or providing any full indemnification to affected individuals and is limited by the Privacy Act in the amount of person medical information that it can provide, RML/NIH will provide full technical assistance to state and local officials in responding to any such incidents and in ensuring that the public health and the health of any potentially affected individuals are protected. While no local or state health agency has indicated that it will seek reimbursement from the NIH for expenses that might result from responding to public health incidents arising from potential exposures of individuals at the RML, the NIH will explore possible mechanisms for reimbursing state and local agencies for any such expenses that arise.

- Notifications will be based on the RML Incident Notification System. A comprehensive description of notifications is detailed in Appendix 2.
    - In the event of any potential exposure in BSL-3 or BSL-4 areas or release of BSL-3 or BSL-4 agents, the Associate Director will notify the Ravalli County Public Health Officer and the head of the Ravalli County Public Health Nursing Department. The County Health Officer and the RML Infectious Disease Adviser will determine the need to notify the public and local or state governmental officials.
    - The Responsible Official for the RML Select Agent Program must notify the Select Agent representative at the CDC in the event of any Select Agent release or exposure, and also complete and submit a "Report of

Theft, Loss or Release of Select Agents and Toxins" form (APHIS/CDC Form 3).

- The RML BEAP, in conjunction with the NIAID/NIH Office of Communication and Public Liaison, will prepare, approve, and release any news statements.

- The RML BEAP will determine the need to collect and quarantine any samples of potentially infectious materials involved in the incident, or to stop laboratory operations in the affected area.
- In the event the incident is related to work with experimental animals, the RML BEAP will determine the need to collect and quarantine any live animals, animal sera, secretions or tissue samples for future analysis.
- The RML BEAP will continue to meet as necessary to monitor the incident, investigate the cause of the incident, and evaluate additional recommendations and other measures needed to resolve the incident, provide for all appropriate internal and outside notifications (Appendix 2), and implement remedial or corrective actions.
- The RML Biosafety Officer will work with the relevant staff to develop a corrective plan to prevent future incidents.
- The RML Infectious Disease Adviser will advise the RML BEAP if observation of close contacts, family members or others is warranted.
- If necessary, the RML BEAP will advise the Associate Director to convene the RML Crisis Management Team.

Meetings of the RML BEAP

- The RML BEAP will meet on an as needed basis as outlined above.
- Meetings will be convened by the Associate Director at the direction of the RML Biosafety Officer.
- The Associate Director, or in his absence the RML senior administrator or equivalent, will chair RML BEAP meetings. In exceptional circumstances, the NIH DOHS may chair the meetings.
- The RML Biosafety Officer serves as the Executive Secretary, and maintains all records, correspondence, and RML BEAP meeting notes.
- The RML Biosafety Officer, with the assistance of other members as needed, will be responsible for preparing a post-exposure incident review on each incident. This report, at a minimum, will contain a description of the incident, all measures taken to deal with the incident, and all recommendations implemented to prevent a recurrence. The RML BEAP will review and approve this report. The review will be forwarded to the proper officials and authorities.
- In the event that the incident involves a Select Agent, the Responsible Official for the RML Select Agent Program must complete and submit a "Report of Theft, Loss or Release of Select Agents and Toxins" form (APHIS/CDC Form 3) to the proper authorities.

- The RML Biosafety Officer will provide a summary of any incident to the RML Institutional Biosafety Committee at the next scheduled meeting.

Exposure Assessment and Management for High Containment

(Under Development)

Section 3. Exposure Risk Assessment

In order to protect RML employees from exposures to biohazards, it is necessary to identify all personnel at risk. At the RML, the principal method by which exposure determination information for laboratory personnel is gathered is with the **Registration of Materials (Potentially) Infectious for Humans** form**.** (Appendix 3)

Procedure for Registering Materials (Potentially) Infectious for Humans

- All Principal Investigators (PIs) working with human pathogens, human blood, body fluids, or tissues, and/or toxins must submit a properly completed registration form to the RML Biosafety Officer for subsequent review by the RML Institutional Biosafety Committee (IBC). For the purposes of this registration, a pathogen is defined as any organism known to or suspected of causing infection in humans, and a toxin is a proteinaceous poison which is highly toxic to humans.
- The IBC will review the registration form to ensure that the material will be manipulated at the appropriate biosafety level, that appropriate equipment is being used, and that the personnel listed have received the proper training. After review and approval, the IBC will recommend to the PI any vaccinations available for the work being proposed. The PI is responsible for ensuring all participating personnel are currently enrolled in the **RML Occupational Health Program** (see Section 4) and have completed all recommended vaccinations and any other recommended medical tests prior to starting laboratory work.
- Information collected on the registration document is annually updated by the Principal Investigator or Supervisor and reviewed by the Biosafety Officer to ensure that exposure determinations are adequately performed and correct. Laboratory surveys and routine walk-through visits of areas are made to ensure that appropriate equipment is being used and procedures are being followed.

Occupational Exposure to Blood

The Occupational Health and Safety Administration (OSHA) Blood Borne Pathogens Standard (29 CPR 1910.1030), requires employers to identify, in writing, tasks and procedures as well as job classifications where occupational exposure to blood occurs. All individuals working in the following jobs are offered the hepatitis B vaccine (see Section 4) and receive appropriate training.

Job Classifications in which all or some of the employees may have occupational exposure:

- Laboratory personnel including Scientists, Post-doctoral researchers, and laboratory
- Law enforcement and emergency response personnel

Tasks and procedures in which employees may have occupational exposure:

- **Security officers**: may face the risk of exposure to blood during the conduct of their duties. For example, at the crime scene or during the processing of suspects, RML security officers may encounter blood-contaminated hypodermic needles or weapons, or be called upon to render emergency aid.
- **First Aide response personnel**: often provide emergency medical services and, therefore, encounter exposures common to those experienced by paramedics and emergency medical technicians. Job duties may be performed hurriedly in the pre-hospital setting under uncontrolled conditions
- **Housekeeping, Maintenance, and other support personnel**: The RML Waste Management Plan describes waste handling procedures at the RML. The implementation of these procedures allows a negative exposure determination to be made for housekeeping, maintenance, and other support personnel. However, in an effort to reduce the chance of illness from an accidental hepatitis B virus exposure, these RML employees are offered hepatitis B vaccine.

Section 4. RML Occupational Health Program

Exposure risk assessments may indicate that an employee needs to be enrolled in one of the specific surveillance programs administered through the RML Occupational Health Program. **Principle Investigators are responsible for ensuring all participating personnel are currently enrolled and have completed all recommended vaccinations and any other recommended medical tests prior to starting laboratory work.**

Job descriptions and responsibilities can change over time. If you think you should be enrolled in one of these programs, please contact your Supervisor, the Occupational Health and Safety Manager (x341), or the Biosafety Officer (x334).

RML Medical Surveillance Program

Serum Storage Program

The **Serum Storage Program** is a surveillance program that provides a reference serum sample for RML employees who may be exposed to human biological hazards at work.

Participation in this program is for RML employees who:

- Work with infectious agents
- Work with human blood or body fluids
- Work with animals

Eligible employees are identified by their supervisors who indicate work responsibilities for position applicants on the Medical Qualification Determination Questionnaire (NIH 750-3) as part of the pre-placement medical evaluation, or by being listed on a **Registration of Materials (Potentially) Infectious for Humans** form (Appendix 3).

Obtaining the Blood Sample

- A 7.5ml blood sample is obtained at the time of the pre-placement medical evaluation. In addition, employees identified on a Registration of Materials (Potentially) Infectious for Humans, who have not donated a blood sample, are notified of their eligibility for this program.
- Additional blood samples may be obtained if an employee reports an occupational injury with potential for infection (e.g. percutaneous or mucous membrane exposure to a body fluid, an animal bite).

Access to Serum Samples

- Serum samples are stored at -20° C in a non-frost-free freezer and retained for 10 years.

- Employees may retrieve their stored serum by signing a medical release.
- NIH investigators may petition the RML Biosafety Officer for access to stored sera.
    - A request for a selected employee's serum sample(s) must be accompanied by the appropriate signed medical release from the involved employee(s).
    - A request for grouped sera must be approved by the Director, Division of Occupational Health and Safety, NIH. The request must be accompanied by:
        - An assessment of the scientific merit of the request by the appropriate Institute peer review group.
        - An assessment of the human subject requirement by the Institute Review Board (IRB), if applicable. Serum will not be released to investigators involved in such studies if doing so would exhaust the stored serum for any individual employee.
    - Employees and NIH investigators who are provided serum samples from the collection are requested to supply information related to the testing of the serum.

Serum Records

Sample records are maintained by the RML Biosafety Officer.

Records maintained for each sample include:

- Employee name
- Date samples were obtained
- Sample number
- Storage location
- Reason(s) for storing the serum
- For serum requests
    - Identifying information for the individual receiving the serum (name, address, phone number)
    - Date serum released
    - Reason the serum was removed
    - Test results
    - Test methodology

Animal Exposure Surveillance Program

The **Animal Exposure Surveillance Program (AESP)** is a mandatory program designed to monitor and support the health of personnel who have direct contact with a variety of animals, their viable tissues, body fluids, wastes or living quarters. RML employees are eligible for AESP if they participate in at least one of the following activities:

- direct care of animals or housing;
- direct contact with animals (live or dead), their tissues, body fluids, or wastes; or,
- work with a zoonotic disease agent.

All employees must report and document bites and scratches promptly to the Management of RMVB (Mike Parnell at ext. 238 or John Bailey at ext. 237). See the **Emergency Response Reference Manual** for first aid procedures. Further information on the AESP may be obtained by calling the Management Team of RMVB.

Tuberculosis Exposure Surveillance Program

The **Tuberculosis Exposure Surveillance Program** (TESP) is a medical surveillance program whose purpose is to minimize transmission of *Mycobacterium tuberculosis* at RML by providing early detection of infection among RML employees and medical evaluation, chemoprophylaxis and referral for clinical care as indicated. Periodic evaluation is mandatory for employees working with *M. tuberculosis* in a laboratory or working with live nonhuman primates. For more information, contact Mike Parnell at ext. 238.

Hepatitis Vaccination Program

Hepatitis B Virus (HBV) Vaccine

A recombinant HBV vaccine is available, free of charge, to all RML employees who may come in contact with blood and body fluids during the performance of their duties. To receive the vaccine, call the Occupational Health and Safety Manager (x431). It is strongly recommended that eligible employees accept the vaccine. The recombinant HBV vaccine does not contain any human blood products; it is both safe and effective. Clinical studies have shown that over 90% of healthy adults administered the vaccine developed antibody to the hepatitis B virus.

The HBV vaccine may also be used prophylactically in combination with hepatitis B immune globulin (HBIG) and is 90% effective in preventing hepatitis B following a documented exposure. Side effects of the vaccine are minimal. The most common complaint (20%) is a sore arm lasting one or two days. A few individuals have reported headache, fatigue, weakness, or rarely, a low-grade fever.

Eligible employees who decline to accept the vaccination must sign the following statement:

> "I understand that due to my occupational exposure to blood or other potentially infectious material I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me."

Further information on hepatitis B and C viruses is provided below. Additional information can be obtained by calling the Occupational Health and Safety Manager (x431).

Hepatitis B Virus

- **Occupationally acquired HBV** - Hepatitis B is the leading occupationally acquired illness among health care workers, affecting approximately 15,000 workers annually. Hepatitis B virus (HBV), formerly known as "serum hepatitis" is one of several viruses that attack the liver producing swelling, tenderness, and sometimes permanent liver damage. HBV is spread primarily through contact with blood and body fluids that contain blood. The virus may also be transmitted via blood transfusion, sexual contact, ear piercing, tattooing, and acupuncture if appropriate precautions are not taken.
- **Symptoms of HBV** - The most frequent symptoms of HBV infection include fatigue, mild fever, muscle or joint pain, nausea, vomiting, loss of appetite, and abdominal pain. Many symptoms suggest a flu-like illness but tend to last longer and jaundice may occur in up to 25% of cases. However, 50% of infected individuals have no symptoms.
- **Risk of HBV Infection** - The risk of HBV infection for RML employees is considered to be high if their jobs entail frequent contact with blood and body fluids. RML employees can protect themselves from occupationally acquired HBV infection by practicing Biosafety Level 2 practices and procedures (Universal Precautions) and by becoming immunized against HBV.

Hepatitis C Virus

- **Signs and symptoms of HCV** - The most frequent symptoms of HCV infection include jaundice, fatigue, dark urine, nausea, loss of appetite, and abdominal pain. Many symptoms suggest a flu-like illness but tend to last longer. However, 80% of infected individuals have no symptoms
- **Long-Term Effects**

  - Chronic infection: 75-85% of infected persons
  - Chronic liver disease: 70% of chronically infected persons
  - Deaths from chronic liver disease: <3%
  - Leading indication for liver transplant
- **Transmission** - occurs when blood or body fluids from an infected person enters the body of a person who is not infected.
  - HCV is spread through sharing needles or "works" when "shooting" drugs, through needlesticks or sharps exposures on the job, or from an infected mother to her baby during birth.
  - Persons at risk for HCV infection might also be at risk for infection with hepatitis B virus (HBV) or HIV.
- **Prevention** - There is no vaccine to prevent hepatitis C. To protect yourself, always follow routine barrier precautions, safely handle needles and other sharps, and get vaccinated against hepatitis B.
- **Treatment and Medical Management** - HCV positive persons should be evaluated by their doctor for liver disease.
  - Interferon and ribavirin are two drugs licensed for the treatment of persons with chronic hepatitis C.
  - Interferon can be taken alone or in combination with ribavirin. Combination therapy, using pegylated interferon and ribavirin, is currently the treatment of choice.
  - Combination therapy can get rid of the virus in up to 5 out of 10 persons for genotype 1 and in up to 8 out of 10 persons for genotype 2 and 3.
  - Drinking alcohol can make your liver disease worse.

Section 5. Exposure Control Methods

Biosafety Levels

Biosafety levels evolved as guidelines to protect microbiological workers and are based on an understanding of the risks associated with practices and procedures involved in working with agents transmissible by different routes. The practices, procedures, and facility requirements associated with different Biosafety levels are described in the CDC/NIH publication **"Biosafety in Microbiological and Biomedical Laboratories (4th ed)" (BMBL)** and are to be adhered to by all RML employees working with potentially infectious material. A copy of this publication should be in all laboratories and is available to all RML employees upon request from the Biosafety Officer (x334). The document is also available online at: http://bmbl.od.nih.gov.

At RML the Institutional Biosafety Committee (IBC) conducts situational risk assessments on a case-by-case basis in order to determine the appropriate biological safety practices and procedures. The Occupational Safety and Health Manager and the Biosafety Officer perform certification of laboratory facilities annually.

All clinical specimens of blood, human tissue, and body fluids are to be handled utilizing Biosafety Level 2 practices and procedures, which equates with the concept of Universal Precautions in the clinical setting. In laboratories working with the human immunodeficiency viruses, other human retroviruses, infected cell lines, and/or simian immunodeficiency virus (SIV) at the research scale, Biosafety Level 3 practices and procedures must be utilized in a certified Biosafety Level 2 facility. Large-scale work with HIV or the other human retroviruses must be performed in a Biosafety Level 3 facility using full Biosafety Level 3 practices and procedures. These requirements extend to all bloodborne pathogens.

Certain laboratory procedures or other factors may require that these organisms be handled at a higher biological safety level than described above. The IBC will conduct situational risk assessments on a case-by-case basis in order to determine the appropriate biological safety practices and procedures.

Fire, emergency response, and law enforcement personnel are required to follow procedures specific for their job categories, as outlined in "**Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis**". Copies of this document are available from the RML Biosafety Officer (x334).

Employee Notification

Employees must be notified of the presence of potentially infectious materials in any workspace. Laboratories and other work areas handling human blood and body fluids and any human pathogens must be posted with an **RML-approved Biohazard Sign**. Work areas are posted by the Biosafety Officer upon completion of a survey and certification of the area at the appropriate biosafety level.

The biohazard sign must be affixed to the entry door and must include:

- Pathogen name
- The biosafety level
- List of personal protective equipment that must be worn in the laboratory
- Any special requirements (i.e. immunizations) required for entry to a workspace
- Any special procedures for exiting the laboratory
- Emergency contact information (name, phone number)

The poster "**3 Emergency Steps to Take in the Event of a Potential Bloodborne Pathogen Exposure"** is to be placed prominently in all work areas where there is a potential for exposure to human blood, body fluids, human retroviruses, or other potentially infectious material. Copies of this poster may be obtained by contacting the RML Biosafety Officer.

Engineering Controls

Engineering controls must be used to eliminate or minimize worker exposure to blood or other potentially infectious materials. At the RML these engineering controls include biological safety cabinets, mechanical pipetting devices, sharps disposal containers, self-sheathing needles, sharps with engineered sharps injury protections, and needleless systems.

Primary Barriers

Class II biological safety cabinets (BSCs) or other physical containment devices are to be used when procedures with a high potential for creating potentially infectious splashes or aerosols are conducted. Such procedures may include centrifuging, grinding, vortexing, blending, sonic disruption, flaming inoculation loops, transferring liquids, homogenizing, withdrawing liquids under pressure, and opening containers of infectious materials having internal pressures different from ambient pressures.

Intranasal inoculations or other animal necropsy may be performed on an open bench if it is determined by the RML Biosafety Officer that conducting the procedure in a biological safety cabinet would place the employee at a significantly increased risk of percutaneous exposure to a blood-borne pathogen. In these cases, strict adherence to mucous membrane protective practices is required, which includes face masks and goggles or face shields with eye protection, as well as using appropriate gloves and protective garments.

Annual inspection and certification of all biological safety cabinets (BSC), fume hoods and other local exhaust ventilation equipment is performed by the Occupational Safety and Health Branch. Trouble calls or questions should be directed to the Occupational Safety and Health Manager at x431.

Procedures for working in a Biological Safety Cabinet (BSC)

- Wear appropriate personal protective equipment. At a minimum, this will include a buttoned laboratory coat and gloves.
- Turn the cabinet on for at least 10 - 15 minutes prior to use.
- Disinfect work surface with suitable disinfectant.
- Place all work items in cabinet before starting work.
- Place items into the cabinet so that they can be worked with efficiently without unnecessary disruption of the airflow, working with materials from the clean to the dirty side.
- Adjust your seat so that your face is above the cabinet opening.
- Delay manipulation of materials for approximately 1 minute after placing the hands/arms inside the cabinet.
- Minimize the frequency of moving hands in and out of the cabinet.
- Do not block air intake or front grillwork.
- Avoid sudden movements as these disrupt the laminar airflow.
- Use an overflow collection bottle with the appropriate disinfectant when using suction. Be sure to have a filter on the discharge side of suction. Clean or dispose of the vacuum filter flask regularly.
- Decontaminate BSC after each use
- Don't store items on top of the BSC. They can damage the filter assembly.

Mechanical Pipetting Devices

Mechanical pipetting devices are to be used for all pipetting activities. Mouth pipetting is strictly prohibited.

Handwashing facilities

RML will provide handwashing facilities, which are readily accessible to employees. When provision of handwashing facilities is not feasible, RML shall provide either and appropriate antiseptic hand cleanser in conjunction with paper towels or antiseptic towelettes.

Needleless Systems

Needleless systems are devices that do not use needles for:

- The collection of bodily fluids or withdrawal of body fluids after venous or arterial access is established;
- The administration of medication or fluids; or
- Any other procedure involving the potential for occupational exposure to

bloodborne pathogens due to percutaneous injuries from contaminated sharps

Devices with Engineered Sharps Injury Protections

Devices with engineered sharps injury protection may utilize non-needle technology or incorporate built-in safety features or mechanisms that effectively reduce the risk of exposure incidents. These devices may be used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids.

Sharps Containers

Puncture resistant sharps containers are to be used at all work sites where needles and syringes, Pasteur pipettes, scalpel blades, razor blades, and other sharps are used. When appropriately filled, the containers are to be autoclaved and than placed in a Medical Pathological Waste (MPW) box for disposal by incineration.

Safety Devices for Centrifuges

For low speed centrifugation of infectious materials, safety centrifuge cups are recommended. If used, the cups are to be loaded and unloaded within a BSC. High-speed centrifugation of infectious materials should be performed using a safety rotor, which is loaded and unloaded within a BSC.

Work Practice Controls

Training and Education

Training for employees, in compliance with the **OSHA Bloodborne Pathogen Standard**, is provided on an annual basis for all laboratory employees or as needed. Principal Investigators and Supervisors are responsible for assuring that all employees under their direction who may be potentially exposed to an infectious agent including bloodborne pathogens attend one of these sessions prior to handling infectious materials and that they receive refresher training on an annual basis. Consult the Occupational Safety and Health Manager for training dates.

Principal Investigators and Supervisors are responsible for job-specific safety training and must document that employees selected for jobs involving manipulation of infectious materials have been adequately trained to perform these tasks.

NIH law enforcement officers receive training consistent with the information provided in the HHS publication entitled "**Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis**". Training is provided upon employment and annually.

Transportation of Infectious Materials

All potentially infectious materials that must be transported between RML and outlying facilities must be packaged and transported according to applicable Federal regulations (42 CFR 72 and 73 and 49 CFR 171-180). Guidance in complying with regulations

pertaining to the shipment of biological materials can be obtained by contacting the Occupational Safety and Health Manager or the Biosafety Officer. Contact the Biosafety Officer prior to any shipments or transfers of biological material identified as Select Agents by the CDC and HHS.

Under no circumstances shall personal vehicles be used to transport infectious materials to or from the RML Campus. Public transportation may not be used. Government vehicle or commercial carrier shall transport materials only.
All containers used to transport infectious materials between laboratories or buildings must be placed in labeled, sealed and unbreakable primary and secondary containers. The containers must be labeled with stickers carrying the international biohazard-warning symbol.

Decontamination and Spill Clean up

All work surfaces where blood, body fluids, any infectious agents or materials are handled must be disinfected daily with an appropriate disinfectant. Additionally, work surfaces must be disinfected after any overt spill. Work surfaces should be covered with plastic-backed absorbent toweling to facilitate clean up and reduce production of aerosols that may result from a spill. Spills within work areas are to be cleaned up by laboratory or research personnel. Housekeeping staff are not authorized to clean up spills of potentially infectious material.

The basic rules for responding to spills in a laboratory are:

- **Tend the injured** - ensure receipt of immediate medical care
- **Isolate the spill** - evacuate the immediate spill area or the entire suite in the case of an aerosolizing spill
- **Contain the spill** - place absorbent material around, on, or in the flow path of the spilled material if it can be done safely.
- **Clean up the spill** – if indicated, allowing time for disinfectants to act
- **Report the spill –** if indicated**,** wait for assistance to proceed with cleanup

Designated BSL-2 Laboratories

In Laboratories where BSL-2 agents are in use, spills inside and outside of biological safety cabinets may be attended to by the staff involved **EXCEPT WHERE OTHERWISE INDICATED**.

In ALL cases, you must report the incident to the Biosafety Officer or Occupational Safety and Health Manager if someone is injured or potentially exposed to the BSL-2 agent! Also, tell the Biosafety Officer if you feel that it occurred as the result of poor practice or equipment failure.

Spills inside biological safety cabinets (BSCs):

- **Small** spills should be immediately wiped up using disinfectant-soaked paper towels or other absorbent material while the cabinet is still running. Allow the disinfectant to act before discarding waste into an autoclave bag for disposal. Do not let the material dry onto the BSC work surface.
- **Larger** spills (e.g. broken culture flasks) are similarly treated, but may require you to stop your work and clean all contaminated surfaces of the cabinet. Leave the cabinet running. Pools of liquid may be covered with disinfectant-soaked paper towelling to absorb the bulk. If your gloves/gown are contaminated, remove these and discard in separate biohazard container for autoclaving. Wash hands and arms thoroughly.
- Discard waste as above, taking care with broken glass.
- Large spills inside BSCs will run into the sump of the cabinet and must not be allowed to dry out. With the cabinet running, lift the work floor and clean its under-surface and the sump floor with disinfectant. Dry with towelling before re-assembly.
- **NOTE: DO NOT USE HYPOCHLORITE-BASED DISINFECTANTS IN BIOLOGICAL SAFETY CABINETS. HYPOCHLORITE IS CORROSIVE TO STAINLESS STEEL.**
- **Report spills of large volumes of infectious material directly to the Biosafety Officer at your earliest convenience. An inspection or re-certification of the BSC may be necessary.**

Spills outside a biological safety cabinet:

- **Small** spills (e.g. drips) occurring within the laboratory and where there has been **NO** significant splashing or personnel contamination should be dealt with as follows –
    - Wearing the appropriate protective equipment (gloves, lab coat, etc.) cover the spill with disinfectant-soaked absorbent toweling or other material.
    - Be careful to avoid cuts with broken glass. To eliminate the potential for cuts use tongs, dust pan or some other device for pickup and carefully discard into an approved sharps container.
    - Using paper toweling, wipe up the spill working from the outside edges toward the center.
    - Clean the spill area again with fresh disinfectant.
    - Place all used materials into Biohazard bags and autoclave.
- **Larger** spills, or any spill which has caused extensive splashing or personnel contamination, should be dealt with as follows –

- Avoid breathing in any aerosols, remove contaminated PPE, and immediately evacuate the laboratory.
- Prevent others from entering the laboratory by placing a **"DO NOT ENTER-BIOLOGICAL SPILL"** sign on the door. The sign should include the date and time of posting and directions to contact the RML Biosafety Officer. No one may return to the spill area unless approved by the BSO.
- **Report the spill to the Biosafety Officer and give as much information as possible (nature of incident, agent involved, location, approximate volume of spill if known, your telephone extension).**
- Depending upon the agent involved and the nature of the incident, the Biosafety Officer may elect to inspect the spill and to arrange clean-up or may direct you to attend to it.
- If approved by the Biosafety Officer, and after at least 30 minutes have elapsed (to allow aerosols to disperse), don protective clothing (gowns, tyvek booties, N95 respirator (if aerosol concern), and gloves), enter the laboratory and cover the bulk of the spill with disinfectant-soaked towels to assist in decontaminating the fluid. Pour disinfectant onto the towel and leave 30 minutes to neutralize the infectious material.
- Mop up the spill using absorbent paper (try to avoid walking in the liquid) by working from the outside edge to the center. Carefully pick up any broken glass or other equipment. Place the waste into appropriate containers (sharps disposal containers, autoclave bags or tote-boxes) for autoclaving. Finally, decontaminate splashed equipment and furniture with disinfectant and paper towels.
- The DO NOT ENTER sign may not be removed, and no work may resume until approved by the Biosafety Officer.

Designated BSL-3 Laboratories

In the BSL-3 laboratories, <u>any</u> spill that results in overt or potential exposure to infectious materials must be reported to the laboratory supervisor, the Biosafety Officer, the Occupational Safety and Health Manager and, if applicable, the RML Select Agent Responsible Official. A written report must be prepared and maintained.

An emergency spill kit must be available within the laboratory. This spill kit shall contain at a minimum: 2 gal of disinfectant; towels; 2 emergency Tyvek suits; rubber gloves; autoclave bags; warning signs and tape; written instructions on procedures for a spill. The spill response section will be posted next to the spill kit.

Racal hoods, warning signs, and tape are to be readily accessible in the

anteroom.

Spills inside biological safety cabinets (BSCs):

- When a spill occurs, the operator should immediately cover the affected area with absorbent pads, tissues or towels to contain the incident and prevent further aerosolization.
- The absorbent material should then be soaked with disinfectant.
- No work should then proceed within the cabinet for at least 15 minutes to allow the cabinet exhaust system to remove aerosols and give sufficient contact time for the germicide to act.
- At the end of this period, the operator should don a second pair of gloves and place all clean up materials (broken tubes, plates, absorbent towels, etc.) into a biohazard bag. All sharp objects or broken materials should be placed in Sharps receptacle prior to bagging.
- Any disposable plastic-ware or tubes that were within the cabinet at the time of the incident should be disposed of as above.
- Any other non-disposable items should be carefully decontaminated with disinfectant followed by 70% ethanol.
- The entire cabinet interior (including grills at front and rear) should be wiped down with disinfectant.
- All biohazard bags should then be autoclaved.

Spills outside a biological safety cabinet:

- When <u>any</u> quantity of potentially infectious aerosol is generated outside the BSC (e.g., by breaking a tube or flask of liquid culture), <u>immediately inform all others working in the suite to leave</u>. (Note that rendering of immediate first aid for life-threatening injuries may take precedence over total, immediate evacuation.)
- Once all individuals have entered the anteroom, all disposable safety clothing is removed and disposed of in a biohazard container.
- Once outside the laboratory, the person responsible for the spill will place a **"DO NOT ENTER-BIOLOGICAL SPILL"** sign on the laboratory door. The sign should include the date and time of posting and directions to contact the RML Biosafety Officer. No one may return to the spill area unless approved by the BSO.
- If overt contamination of body, shower thoroughly.
- <u>Decontamination and Clean Up</u>
    - Personnel assigned to effect decontamination/clean-up (spill responders) will follow these procedural guidelines under the direction of the suite supervisor and/or Biosafety Officer:

- After initial evacuation, allow a minimum of 2 hours elapsed time after spill to permit settlement and elimination of aerosolized particles.
- Put on Racal hood and appropriate PPE and reenter the suite.
- Place disinfectant-soaked absorbent toweling over affected area. Gently flood entire spill area (extend beyond affected area) with disinfectant and allow sufficient contact time. Wipe down floor, walls, sink, and other exposed surfaces with disinfectant. Collect all contaminated materials in appropriate biohazard containers. Place containers in autoclave and start cycle before exiting suite.
- Proceed to anteroom and remove clothing and equipment. All material used for cleanup will be decontaminated or transferred to the autoclave and sterilized. Shower thoroughly.
- In consultation with the Biocontainment Exposure Assessment Program (BEAP) the Biosafety Officer may order additional decontamination procedures. At a minimum, after cleanup of the spill area, a minimum of 4 hours must elapse before resuming work in the suite.
- The DO NOT ENTER sign may not be removed, and no work may resume until approved by the Biosafety Officer.
- The BSL3 logbook record of the incident will be updated with details of all remedial actions undertaken.

Spills in laboratory centrifuges

Failure of tubes and rotors during centrifugation can be the cause of significant aerosol production. If a failure is suspected **during** a centrifuge run –

- Immediately switch the machine off and allow the rotor to come to rest.
- **DO NOT OPEN THE CENTRIFUGE.**
- Avoid breathing any aerosols and evacuate the immediate area.
- Proceed as above for spills outside of a BSC.

If a spill is discovered **after** opening the centrifuge, or is visible through a transparent lid:

- Avoid breathing any aerosols and immediately close the centrifuge if open.
- Evacuate the immediate area and proceed as above for spills outside of a BSC.

In the event of a spill of infectious material in a public access area (hallway, elevator, etc.) keep all persons away from the spill area and contact the Biosafety Officer and/or Occupational Safety and Health Manager for guidance regarding handling and clean up.

Infectious Waste Disposal

All infectious waste will be chemically deactivated and autoclaved (see below). All employees shall comply with the guidance given in the **RML Waste Management Plan**. Additional copies of this document are available from the Occupational Safety and Health Manager.

Autoclave procedures

Be sure you know how to run the autoclave before using!

Solid Waste

- Place all solid waste for autoclaving in TWO orange biohazard bags. DO NOT OVERFILL
- NO SHARPS (needles, broken glass) in autoclave bags. Use a sharps container and/or broken glass box instead.
- Close bag loosely with rubber bands or autoclave tape (steam cannot penetrate the bag if it is wrapped too tightly).
- Attach a red "**Medical Pathological Waste**" sticker to each bag of waste (attach with autoclave tape since the adhesive on the sticker loses adhesiveness during autoclaving). Write your name and room number on this tag.
- Handle bags by the top. Place a shallow tray under each item to contain spills. Do not overload the autoclave.
- Use at least one **Steam Sterilizer Integrator** per load. Don't depend on the sterility indicator on the bag or autoclave tape. They only reveal that the sterilization temperature was reached but not for how long.
- Add an "Odo-Clave" deodorant pad to each load to minimize stench.
- Autoclave using proper "Waste" cycle.
- Always wear protective gloves when unloading autoclave.
- Stand back as door opens to avoid scalding by released steam.
- Remove autoclave bags promptly. Keep them well segregated from bags that have not been autoclaved to avoid any possible confusion.
- Once the material has been autoclaved and cooled place in a secondary clear bag and transfer to the white plastic totes located south of building 5.

- **Liquids**

- Liquid waste: add small amount of Roccal or other disinfectant (NO BLEACH!) to each container, place autoclave tape on all items, and write “WASTE” on all items.
- Loosen caps
- Autoclave using proper “Liquids” cycle
- When cycle is finished, open door and wait at least 10 min. before removing items to minimize the risk of explosion due to super-heated liquids.

Equipment Repair and Transfer

All equipment which may have been exposed to hazardous materials (i.e., known hazardous chemical, radiological, or biological substances) must be appropriately decontaminated and certified as being clear of hazards, using NIH Form 2683 before transfer, service, or repair is done. These forms are available from the Occupational Safety and Health Manager, the Biosafety Officer, or the Radiation Safety Officer. Included is all scientific/medical equipment and any office furniture/equipment or supplies that have been used in clinical areas, laboratories, or other potentially hazardous locations.

Personal Protective Equipment

A variety of personnel protective equipment in a variety of sizes is available to all RML employees through the RML Stockroom or through the vendor catalogs. All personnel are encouraged to discuss their needs, with regard to personal protective equipment, with the Occupational Safety and Health Manager at x431. If equipment is required, which is not currently available through the RML stock room or vendor catalog, it is to be ordered from the appropriate source at no cost to the employee. However, personal preference is not justification for special ordering of personal protective equipment.

Gloves

Gloves are to be worn by all employees when directly handling potentially infectious material or when in contact with contaminated surfaces. Vinyl examination gloves, surgical latex, or nitrile gloves may be chosen by the employee based on individual need. Gloves are to be changed routinely and rigorous hand washing policies established in laboratory areas. Employees must inspect gloves routinely and replace them whenever they are visibly soiled, torn, or punctured. All gloves are to be discarded into the medical pathological waste (MPW) stream. Hands are to be washed when gloves are changed or removed on completion of work.

Other Protective Garments

Laboratory coats, gowns, aprons, or suits, whichever is most appropriate for the particular application, are to be worn by all personnel manipulating or otherwise handling infectious or potentially infectious materials. These garments are not to be

worn outside of the laboratory area unless the employee is transporting hazardous material. After disposable protective garments are used, discard them in the MPW stream as described in the **RML Waste Management Plan**. Cloth laboratory coats are not to be taken home by the employee for laundering. The RML provides laundry service for laboratory coats, uniforms, and linens. Contact your supervisor for details related to obtaining information about this service and acquire pick-up and delivery schedules for each building.

Respirators

Respirators must not be used in the laboratory without prior approval of the Occupational Safety and Health Manager. Supervisors are not authorized to select or recommend the use of respiratory protection, regardless of the type. Call the Occupational Safety and Health Manager if you feel respiratory protection is required. Surgical facemasks, used for mucous membrane protection, are not considered respirators and are not to be used in situations where respiratory protection is required. All respirator users must be enrolled in the **RML Respiratory Protection Program**. Each lab will supply and maintain the recommended respiratory protective device.

Section 6. Appendices

Appendix 1: RML Incident Investigation Report Form (DRAFT)

Provided as Appendix 10 of ERP.

Appendix 2: RML Incident Notification System (DRAFT)

Provided as Appendix 6 of ERP.

Appendix 3: Registration of Material (Potentially) Infectious for Humans

Registration of Materials (Potentially) Infectious for Humans **HPRD NUMBER**

The NIH Institutional Biosafety Committee, in conjunction with the NIH Scientific Directors, maintains a registry of all laboratories and personnel working with human pathogens, and/or toxins, human blood, body fluids, and tissues. For purposes of this registration, a pathogen is defined as any organism known to or suspected of causing infection in humans, and a toxin is a proteinaceous poison which is highly toxic to humans.

The **Principal Investigator (PI)** is responsible for completing the appropriate parts of this registration document, including first name, last name, and last four digits of the Social Security Number (SSN) for each individual associated with the work involving potentially infectious materials. This is needed to maintain a listing of persons at risk of exposure and for use by the Occupational Medical Service (OMS) in maintaining personnel medical records.

This registration document is to be forwarded to the NIH Biosafety Officer prior to the initiation of work. Each individual listed should personally initial this document to indicate that they have been informed of the potential hazards associated with this work, the appropriate safety practices to be used, the availability of occupational medical programs, and applicable training requirements.

The PI is also responsible for notifying the Occupational Safety and Health Branch (OSHB) when work with any potentially infectious material is terminated or when other significant changes occur, such as changes in personnel or relocation of the laboratory.

The OSHB conducts an annual survey of registered laboratories to review practices and procedures associated with this work. The survey is not intended to negate the responsibilities of the PI in supervising work with potentially infectious or hazardous material. For help call OSHB 496-2346.

PART A To be completed for each laboratory room Please send original to Occupational Safety and Health Branch

Laboratory Address		Telephone 406-	Fax 406-	Please check your Institute, Center, or Division
Building(s)	Room Number			☐ NIAID NIAMS NICHD NIDDK NIMH
Mailing Address/Office Address		Fax 406-	Mail Stop Code	NCRR CC FDA OD NHGRI
Building	Room / Telephone 406-			NIDCR NEI NHLBI NIA NIAAA
				NCI NIGMS NINDS NIDCD

Provide the following information on all personnel working with registered materials, in this laboratory room (please print) Division: DIR Branch: RML Section:

Last Name	First Name	Last 4 digits of SSN	E-mail	Employee's Initials*
(PI)			@niaid.nih.gov	
			@niaid.nih.gov	
			@niaid.nih.gov	
			@niaid.nih.gov	
			@niaid.nih.gov	
			@niaid.nih.gov	
			@niaid.nih.gov	
			@niaid.nih.gov	
			@niaid.nih.gov	

***Employee will personally initial when informed of potential hazards, safe work practices, availability of medical surveillance, and has attended the NIH course "Working Safely With HIV and other Bloodborne Pathogens". (Attach sheets as necessary.)**

PART B To be completed by PI for laboratories handling potential human pathogens and/or toxins. Please provide information for each microorganism and/or toxin used in this laboratory. (Attach additional sheets as necessary)

Organism	Strain	Volume used	Recombinant DNA Registration Number

Toxin	Volume Used

Human Blood and Body Fluids

Is organism concentrated? (Y/N) Specify methods:

Centrifugation ☐ Filtration ☐ Precipitation ☐ Other ☐ _____

Containment Equipment available:

Biological Safety Cabinet: Class I ☐ Class II ☐ Class III ☐ Fume Hood ☐ Containment Centrifuge ☐

Other _____

HPRD NUMBER

List animals used in this laboratory	What live organism, toxin, and/or recombinant material is injected	Specify routes of administration SC	IM	IP	IV	IC	Aerosol	Other	Building	Room
		☐	☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐	☐			

Animal Study Proposal Number(s)

Have laboratory personnel attended a course on "Using Animals in Intramural Research?" ☐ No ☐ Yes
If no, call your ICD Veterinarian for information about animal care and use requirements

(Use continuation sheet as necessary)
Types of animal tissue handled:
_____

I accept responsibility for the safe use of all potentially infectious organisms at Biosafety Level _____ and have informed all personnel of the risks of exposures while working with these organisms and/or toxins.

_____
Principal Investigator (signature) Date

PART C To be completed by PI when laboratory procedures involve the handling of human blood, body fluids, and/or tissues

Type(s) of human samples manipulated: ☐ Blood ☐ Urine ☐ Spinal Fluid ☐ Tissues ☐ Serum ☐ Feces ☐ Semen ☐ Other(s) _____

Type(s) of manipulations: ☐ Centrifugation ☐ Blending/Mixing ☐ Dissection ☐ Sonication ☐ Pipetting ☐ Other(s) _____

I accept responsibility for the safe use of human blood, body fluids, and/or tissues using Biosafety Level 2 practices and procedures. All personnel have been informed of potential risks, proper laboratory practices, and have attended "Working Safely with HIV and Other Bloodborne Pathogens".

_____
Principal Investigator (signature) Date

PART D To be completed by the RML Institutional Biosafety committee and the Occupational Safety and Health Branch

Reviewer's comments:

_____

_____

_____

Parts A and B of this document were reviewed by the RML Institutional Biosafety Committee and/or their designee

On _____ work can proceed in a BSL _____ facility using BSL _____ practices and procedures. Animals
Date

will be handled at ABSL _____

_____
Chair, RML Institutional Biosafety Committee

On _____ this laboratory was certified at Biosafety Level _____
Date

_____
Occupational Safety & Health Specialist/Industrial Hygienist

On _____ this animal facility was certified at Animal Biosafety Level _____.
Date

_____
Occupational Safety & Health Specialist/Industrial Hygienist

PART E To be completed by OSHB upon notification that work in this laboratory is terminated

The date this document was inactivated: _____

_____
Occupational Safety & Health Specialist/Industrial Hygienist

(BACK) Return completed form to RML Biosafety Officer, OAD, 6-311
OSHB 6/99